

## **REMARKS**

### **Status of the Claims**

Claims 13-24 are currently pending and under examination. Claims 1-12 and 25 have been canceled without prejudice or disclaimer to the subject matter claimed therein.

### **Amendment to the Claims**

Claim 13 has been amended. Representative support can be found in the specification at page 7, lines 1-7. The amendments to the claims do not add prohibited new matter.

### **Rejection under 35 U.S.C. § 112, first paragraph**

Claims 13-24 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to distinctly point out and claim the subject matter regarded as the invention.

The Office Action alleges that claim 13 is vague and indefinite. Without acquiescing to the propriety of the rejection and solely to advance prosecution of the application, claim 13 has been amended. Claim 13, as it stands, is not vague and indefinite. Applicants respectfully submit that the activation is of the combined oocyte and treated nucleus during metaphase of the recipient oocyte that reconstitutes the embryo. It is therefore respectfully requested that this rejection be withdrawn.

### **Rejection under 35 U.S.C. § 103(a)**

Claims 13-24 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious under Wangh (U.S. Patent 6,753,457) in view of Samocha-Bone (Molecular Human Reproduction 4: 133-137, 1998).

The Office Action alleges that it would be obvious to combine the methods of reprogramming nuclei in somatic cells as disclosed by Wangh with the methods for treating sperm nuclei disclosed in Samocha-Bone to arrive at the claimed invention.

The Office Action acknowledges that Wangh does not disclose use of polyanions without the use of CSF. The Office Action however alleges that at the time of filing the present application, the use of polyanions to cause chromatin decondensation to allow DNA to bind to maternal histones was known.

The Office Action alleges that Samoch-Bone discloses nuclear swelling and chromatin decondensation of sperm using polyanions. Samocha-Bone discloses methods for nuclear decondensation of spermatozoa with the use of heparin, a polyanion, and reducing agents (beta-mercaptoethanol). The claimed invention however, is a complete and closed series of steps useful for preparing a reconstituted embryo. Accordingly, the use of a reducing agent is excluded.

The Office Action alleges that the closed language of the claims is not to the exclusion of reducing agents as the steps are not required to recite each and every compound used in carrying out the invention and that closed language does not preclude obviousness to remove unnecessary agents.

It is respectfully submitted that the claims recite closed language. MPEP 2111.03 states that “the transitional phrase ‘consisting of’ excludes any element, step, or ingredient not specified in the claim.” This section of the MPEP further states that the only additional elements or steps allowed are those unrelated to the claimed invention. Accordingly, the inclusion of a reducing agent is indeed related to the invention, and it is accordingly excluded based on Applicants use of closed claim language.

The Office Action also alleges that it is obvious to omit unnecessary agents in treating the cells. Applicants respectfully submit that at the time of filing the addition of a reducing agent was not deemed as an unnecessary agent. Indeed, reducing agents are used to primarily reduce thiol bonds, which are often key in allowing a folded protein to open. Further, the Office Action alleges that some agents are obvious to omit, such as aqueous buffers. Applicants respectfully agree and point out that Samocha-Bone also does not mention buffers on page 135, col. 1, last paragraph, but does mention heparin and beta-mercaptoethanol, indicating that these ingredients are necessary.

The Office Action further alleges that the omission of reducing agents is disclosed by the references of Delgado, Reyes and Lassalle. It is submitted that these references do not demonstrate what the Office Action purports them too. Firstly, Delgado was published after the priority date of the claimed invention, and accordingly does not represent what was known in the art at the time of filing. Reyes involves experimentation with full sperm cells, not with sperm

after controlled proteolysis. As Delgado demonstrates, there are significant differences between treating the nucleus only and with treating a full sperm cell. This is further illustrated in that Reyes shows heparin decondensation after 22 hours, whereas the working examples in the present application demonstrate decondensation after 30-60 minutes (*see*, page 6, last paragraph). Accordingly, one skilled in the art would not appreciate that the steps described by Reyes would be applicable or suitable following controlled proteolysis. Similarly, Lassalle treats full spermatozoa and not spermatozoa following controlled proteolysis. Accordingly, none of these references demonstrate that at the time of filing, one would have considered using a reducing agent on a somatic nucleus that has undergone controlled proteolysis. Furthermore, these references demonstrate that heparin alone requires a significantly longer period of time for decondensation. Thus one skilled in the art would readily conclude that the combination of a reducing agent and heparin is the most efficient means to induce nuclear swelling.

Further, with regard to the combination of the references, Wangh discloses methods for diploid nuclei whereas the present invention is directed to somatic haploid nuclei. As discussed previously, diploid and haploid nuclei, and in particular sperm nuclei have very different properties. Wangh further teaches methods for an amphibian cell, whereas the claimed invention concerns mammalian cells. Wangh does not teach or suggest reconstituting a mammalian embryo, but instead concerns methods for reconstituting a diploid amphibian cell. Applicants also note that the heart of the invention of Wangh concerns the use of egg extracts to induce changes. Accordingly, given the teachings of Wangh, one skilled in the art would not have expected the use of egg extract to be unnecessary for inducing nuclear swelling.

In summary, there is no reasonable expectation of success in arriving at the claimed invention through combining the cited references. Firstly, an amphibian oocyte is not the same as a mammalian cell. Secondly, Wangh teaches the use of egg extracts for reconstituting cells. Accordingly, one skilled in the art would not have considered the egg extracts heralded by the disclosure of Wangh to be irrelevant. Thirdly, the cited references teach that the combination of a reducing agent and heparin to be more effective in inducing nuclear swelling than either a reducing agent or heparin by itself. Thus, one skilled in the art would not have considered the use of a polyanion alone. Accordingly, Applicants believe that the combination of references is

far too tenuous to allow one skilled in the art to arrive at the claimed invention. It is therefore respectfully requested that this rejection be withdrawn.

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, she is invited to telephone the undersigned at their convenience.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: **January 14, 2010**  
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Respectfully submitted,  
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